

# **EXHIBIT B**

1                   IN THE UNITED STATES DISTRICT COURT  
2                   FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
3                   AT CHARLESTON

4  
5   IN RE: ETHICON, INC.,                   Master File No.  
6   PELVIC REPAIR SYSTEM PRODUCTS       2:12-MD-02327  
7   LIABILITY LITIGATION                 MDL 2327

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9   THIS DOCUMENT RELATES TO CASE  
10   CONSOLIDATION:  
11   Terreski Mullins, et al., v.  
12   Ethicon, Inc., et al.  
13   Case No. 2:12-CV-02952

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17                   DEPOSITION OF  
18                   VLADIMIR IAKOVLEV, M.D.

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20                   \* \* \* \*

21                   HIGHLY CONFIDENTIAL PORTION

22                   \* \* \* \*

23

24                   September 11, 2015

25                   9:00 a.m. - 5:05 p.m.

1                   A.    They were kept in formalin, in a  
2    jar, and then they were put in the cassette for  
3    tissue processing and then they went through the  
4    whole process of xylene alcohol and everything else  
5    and then I had slides made.

6                   Q.    And no analytical chemistry done  
7    of that control, correct?

8                   A.    Why would I?  I'm doing histology.

9                   Q.    I understand.  No analytical  
10   chemistry; is that correct?

11                  A.    That is correct.

12                  Q.    Thank you.  Number 19.

13                  A.    Yes.

14                  Q.    "Request all materials related  
15   to testing of intentionally oxidized  
16   polypropylene that had not been  
17   implanted or exposed to formalin."

18                  Do you see that?

19                  A.    Yes, I do.

20                  Q.    Is there any information on  
21   Exhibit No. 4 related to that kind of testing?

22                  A.    No, because the test is still in  
23   progress.  I mean, I kept part of mesh in different  
24   solutions and I haven't taken them out yet.  I  
25   haven't examined them yet.

1 Q. Okay. Tell me what that  
2 experiment does?

3 A. I did the same thing as I did for  
4 formalin exposure. I took pieces of mesh and put  
5 them in solutions of hydrogen peroxide, hydrogen  
6 peroxide with catalysts, few strong acids,  
7 solvents, and just they are stored in these  
8 solutions.

9 Q. How many pieces of mesh are you  
10 testing?

11 A. It's hard to say now. It might be  
12 over 20 small pieces.

13 Q. And how are they stored right now?

14 A. In a dark room in a cabinet.

15 Q. In a vial?

16 A. What do you mean, vial?

17 Q. Are they in a container with a  
18 cover on them?

19 A. Yes, of course. Some of them are  
20 acids and they're in glass containers.

21 Q. What temperature are they being  
22 stored?

23 A. Just room temperature.

24 Q. Do you have a protocol that you  
25 wrote up for this test?

1                   A.    No.   The only protocol I used was  
2   there was a published paper, they introduced this  
3   stimulated body environment -- simulated, not  
4   stimulated.   Simulated body environment.   Hydrogen  
5   peroxide was the catalyst.   Catalyst is a chromium  
6   salt.

7                   Q.    Cobalt chloride?

8                   A.    Probably.

9                   Q.    That's Dr. Guelcher's paper?

10                  A.    I'm not sure if it's his paper,  
11   it's another paper.   But anyway, I'm testing his  
12   protocol.   I followed exactly the description in  
13   the paper and kept it in the solution for almost a  
14   year by now, but it's still too early to take it  
15   out.

16                  Q.    Why is it still too early to take  
17   it out?

18                  A.    Because based on my analysis of  
19   the specimens explanted from the body I can barely  
20   see the degradation bark after a year in the body.  
21   So if I take them now it would be too early.

22                  I may just waste samples, so I have to  
23   wait for probably a few extra months or maybe  
24   another year.   Because by year two or 1 1/2 years  
25   in the body, the bark becomes visible in

1 100 percent of the cases.

2 If I take them out by 12 months, I may  
3 or may not see something and then it would -- I'll  
4 just waste samples.

5 Q. Did you prepare the solution in  
6 which these samples are stored?

7 A. Yes, I did.

8 Q. And what is the recipe for the  
9 solution that you used?

10 A. It's written in the original paper  
11 I used for the --

12 Q. Can you tell me what the original  
13 paper is?

14 A. I'd have to check now.

15 Q. And how many samples are stored?

16 A. As I said, probably over 20.

17 Q. And how many different kinds of  
18 mesh are being tested?

19 A. There is one from one  
20 manufacturer, and then -- four types of mesh.

21 Q. How many Ethicon meshes are being  
22 tested?

23 A. At least one.

24 Q. What kind?

25 A. It's written on the jars. I may

1 have to check later.

2 Q. Doctor, do you have an inventory  
3 of what's in each vial written down?

4 A. It's written on the jar.

5 Q. Is it written down on a piece of  
6 paper anywhere?

7 A. No.

8 MR. ORENT: Objection.

9 BY MR. THOMAS:

10 Q. Is it written in a computer  
11 somewhere?

12 A. No, just on jars. Jars label when  
13 the case was put and what type of mesh was put in.

14 Q. When did you start this  
15 experiment?

16 A. Last September.

17 Q. So it's been a full year?

18 A. Yes.

19 Q. And did you put the mesh in this  
20 solution in these 20 or so samples all at the same  
21 time?

22 A. Within two weeks.

23 Q. All right. As I understand it,  
24 there are at least four different mesh  
25 manufacturers that are a part of this experiment?

1                   A.    At least four different type of  
2 mesh. I would have to check with the labels what  
3 is written there, what manufacturers, what mesh was  
4 put in there. I don't remember. It's been a year.

5                   Q.    Are you working with anybody else  
6 on that experiment?

7                   A.    No.

8                   Q.    This is solely your work?

9                   A.    Yes.

10                  Q.    Did you consult with anybody about  
11 the kind of solution that you would use for your  
12 experiment?

13                  A.    No. Whom I would consult? Nobody  
14 did it before. The only information I extracted  
15 was from that specific simulation body environment  
16 simulation from the paper.

17                  Q.    You know Dr. Guelcher has tried to  
18 insulate oxidized polypropylene, don't you?

19                  MR. ORENT: Objection.

20                  THE WITNESS: I know that he did an  
21 experiment, and he asked me what I see. I said  
22 it's too early, I'm not going to take them out yet.  
23 I will keep them a little longer.

24                  BY MR. THOMAS:

25                  Q.    Did Dr. Guelcher tell you he had



1 intentionally oxidized polypropylene by exposing it  
2 to some chemical solution?

3 MR. ORENT: Objection.

4 THE WITNESS: Yes, he did.

5 BY MR. THOMAS:

6 Q. Did you ask him to have that mesh  
7 so that you could determine whether this  
8 intentionally oxidized polypropylene absorbed  
9 stain?

10 MR. ORENT: Objection.

11 THE WITNESS: No.

12 BY MR. THOMAS:

13 Q. Why not?

14 MR. ORENT: Objection.

15 THE WITNESS: Because I'm doing my own  
16 experiment and I believe I need to keep it for at  
17 least a year and a half.

18 BY MR. THOMAS:

19 Q. Did you discuss with Dr. Guelcher  
20 the scope of his experiment?

21 MR. ORENT: Objection. At this point,  
22 Counsel, I think you're getting into -- I think you  
23 need to clarify whether your questions are in the  
24 context of litigation or research.

25 To the extent it's in litigation it's

1 covered by privilege and I would instruct the  
2 witness not to answer under the rules. But to the  
3 extent that you're discussing research, I think  
4 that's fair game to discuss.

5 BY MR. THOMAS:

6 Q. Okay. From a research  
7 perspective, did you have any discussions with Dr.  
8 Guelcher about his experiment?

9 A. It's work in progress so it's  
10 privileged to researchers, I guess, at this point.

11 Q. Are you going to assert a  
12 privilege for your research?

13 A. For research information, yes.

14 Q. Okay. And you asserted a  
15 litigation privilege, which I don't think is  
16 appropriate -- I'm not arguing with you. You said  
17 there's no research privilege. Now he's trying to  
18 assert a research privilege?

19 MR. ORENT: No, what I said was in  
20 terms of legal -- in terms of legal privileges that  
21 I can, that I have, that I have an attorney-client --  
22 excuse me, a attorney work product under the Rule  
23 26.

24 Rule 26 specifically allows for expert  
25 witnesses to consult with one another under the

1 2010 amendments to the federal rules.

2 So, what I was clarifying is that it is  
3 my privilege to seek and to utilize for my client,  
4 and that's what I was exercising with regard to  
5 non-research thought processes for litigation.

6 To the extent Dr. Iakovlev has  
7 proprietary interests in research that is ongoing  
8 or may be ongoing, that's up to him as to whether  
9 or not -- and I know that on both sides in this  
10 mesh litigation have previously taken a position  
11 that those sort of things are not discoverable.

12 To the extent the doctor is  
13 comfortable, I'd be happy to designate this portion  
14 of the transcript highly confidential and allow the  
15 witness to answer.

16 THE WITNESS: I also need to add that  
17 that experiment is not in my opinions. I was not  
18 base my opinions on any part of that experiment.  
19 And I'm not really sure why you asking me these  
20 questions.

21 BY MR. THOMAS:

22 Q. Because I get to ask them.

23 MR. ORENT: If I can just have a minute  
24 with the witness and explain what the highly  
25 confidential designation means, that may clarify

Vladimir Iakovlev, M.D.

1 this.

2 MR. THOMAS: Thank you.

3 -- RECESS AT 9:42 --

4 -- UPON RESUMING AT 9:43 --

5 MR. ORENT: We can go back on the  
6 record.

7 I'll just say for the record over the  
8 break I just explained to Dr. Iakovlev what the  
9 highly confidential designation is and that all the  
10 lawyers in this litigation have all signed on to  
11 it.

12 Confidentiality agreement whereby there  
13 are limited distribution on each side as to who can  
14 receive highly confidential information and that  
15 after discussing it I believe the witness is  
16 comfortable with the designation and will proceed  
17 to answer.

18 BY MR. THOMAS:

19 Q. Thank you. Have you have  
20 discussed with Dr. Guelcher the results of his  
21 test?

22 A. Yes, I asked him what he saw.

23 Q. And what did he tell you?

24 A. He said that there is flaking on  
25 the surface early, it's not confluent but there are

1 some flakes forming.

2 I said it might be too early, because  
3 he did it I think on six weeks or so, maybe more,  
4 maybe up to three months.

5 I said, well, I keep my specimens for  
6 at least a year and a half because I believe that  
7 that's much time you need to make it visible by my  
8 techniques. Maybe by SCM we can see a little bit  
9 earlier, and we stopped at that.

10 Q. Do you know whether he conducted  
11 any analytical chemistry testing on any of the mesh  
12 he analyzed?

13 A. I think he did.

14 MR. ORENT: Objection.

15 THE WITNESS: I don't remember at this  
16 point. It's not my specifically methodology, so I  
17 didn't do these things.

18 BY MR. THOMAS:

19 Q. Did you have discussions with Dr.  
20 Guelcher about trying to stain the polypropylene  
21 that he had intentionally oxidized?

22 A. He asked me. I said it's too  
23 early.

24 Q. Okay?

25 A. So I said maybe by your methods

1     you can detect it. By my methods, probably I  
2     cannot. And I said I will keep my pieces for  
3     longer and then we'll see what happens.

4                   Q.     And how did you decide -- strike  
5     that. Did I understand you to say that you have  
6     chosen 18 months as the time when you think it will  
7     be appropriate to test for oxidation?

8                   MR. ORENT: Objection to form.

9                   THE WITNESS: Yes.

10                  BY MR. THOMAS:

11                  Q.     And at 18 months is it your  
12     intention to remove all of those meshes from the  
13     chemical solution and determine whether it's  
14     intentionally oxidized?

15                  A.     Part of it. Probably not all of  
16     them in one shot. I will start taking some pieces  
17     and examining them see what happens and if I --  
18     depends on what I see, I may keep them longer.

19                  Q.     And what kind of tests do you  
20     propose to run on them after 18 months?

21                  A.     Histology, what I've done -- what  
22     I showed in the paper.

23                  Q.     The same kind of tests that you've  
24     run on the meshes that are contained in your  
25     reports?

1 A. Similar.

2 Q. Any differences?

3 A. Don't plan on anything different  
4 at this point. I may, I mean, it's work in  
5 progress research. Maybe I'll find something else,  
6 I don't know.

7 Q. Are you consulting with anybody  
8 else on this particular experiment?

9 A. We discussed it only with Scott  
10 Guelcher.

11 Q. And is the mesh that's being  
12 tested pristine new mesh?

13 A. Yes.

14 Q. Never been exposed to tissue?

15 A. That is correct.

16 Q. Never been exposed to formalin?

17 A. That is correct.

18 Q. Who is paying for this testing?

19 A. Nobody. I just took chemicals  
20 from our histo lab.

21 Q. Did counsel fund this experiment?

22 A. No, there is no additional  
23 funding. What funding would I need for it?  
24 Chemicals are in the lab.

25 Q. Where did you get the mesh?

1                   A.    They came from some law firms  
2    during earlier cases.

3                   Q.    Okay.  And where did you get the  
4    chemicals?

5                   A.    I said, they are in the lab.

6                   Q.    Okay.  So you used materials from  
7    the St. Michael's histo lab to put them, and you  
8    combined those chemicals in a recipe that you're  
9    now exposing this polypropylene to?

10                  A.    That is correct.  These are  
11   regular chemicals that are used in histo lab.

12                  Q.    And the reason why you're doing  
13   this test is to determine whether, first, after  
14   18 months this polypropylene will oxidize due to  
15   exposure to this chemical mixture, correct?

16                  A.    Could you repeat the question?

17                  MR. THOMAS:  Can you read it back?

18                  -- REPORTER'S NOTE:  Question read back  
19   as recorded above.

20                  THE WITNESS:  That's correct.

21                  BY MR. THOMAS:

22                  Q.    And how will you determine whether  
23   it's oxidized?

24                  A.    I would see degradation layer on  
25   the surface.



1 Q. And that would be by light  
2 microscopy?

3 A. Yes.

4 MR. ORENT: Objection.

5 BY MR. THOMAS:

6 Q. Any other analytical technique  
7 that you propose to use?

8 A. As I said, none at this point.

9 Q. And as a part of your experiment  
10 do you then intend to see whether -- if you are  
11 able to oxidize polypropylene, according to your  
12 visual observation by light microscopy, will you  
13 then see whether the oxidized polypropylene holds  
14 stain?

15 A. Yes, that's the way to see it.  
16 This just becomes porous and after absorbs stain.

17 Q. And the way you will test that is  
18 the same way you've processed the slides in Exhibit  
19 No. 1 and 2 -- you'll put them through the sample  
20 preparation histology analysis that you've done in  
21 all your other cases?

22 A. Can be tried without putting them  
23 through histology; you can immerse exposed mesh  
24 into the dye solution.

25 Q. Just drop it in the jar?

1                   A.     Pretty much. If it stains, then  
2     you can see staining on the surface. That means  
3     there is a layer of porous polypropylene on the  
4     surface.

5                   It's like, this is not stain, this is  
6     anodized aluminum. So there's porous layer on  
7     aluminum. If you drop unprepared aluminum in the  
8     jar with black ink it will not absorb anything  
9     because it's sealed.

10                  If you drop it with anodized layer it  
11     will become black because it will absorb it. It's  
12     the same technique; it's pretty basic.

13                  Q.     I understand. Thank you.

14                  Are you aware of a method where you can  
15     take a piece of pristine mesh that's been exposed  
16     as you've described, and prepare a histological  
17     slide of that exposed material without embedding it  
18     in some other medium?

19                  A.     Let me ask you if I got your  
20     question right.

21                  Am I aware of a histological technique  
22     which will allow me to cut through the mesh without  
23     embedding it into anything?

24                  Q.     Correct.

25                  A.     No. It has to be embedded into

1 CERTIFICATE OF REPORTER

2 CANADA )

3 PROVINCE OF ONTARIO )

4

5 I, Judith M. Caputo, the officer before whom the  
6 foregoing deposition was taken, do hereby certify  
7 that the witness whose testimony appears in the  
8 foregoing deposition was duly sworn by me; that the  
9 testimony of said witness was taken by me in  
10 shorthand, using Computer Aided Realtime, to the  
11 best of my ability and thereafter reduced to  
12 written format under my direction; that I am  
13 neither counsel for, related to, nor employed by  
14 any of the parties to the action in which the  
15 deposition was taken, and further that I am not  
16 related or any employee of any attorney or counsel  
17 employed by the parties thereto, nor financially or  
18 otherwise interested in the outcome of the action.

19

20

21 \_\_\_\_\_

22 Judith M. Caputo, RPR, CSR, CRR

23

24 Commissioner for taking

25 Oaths in the Province of Ontario